

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

CAROL LEWIS,

Plaintiff,

v.

SYLVIA MATHEWS BURWELL  
Secretary of the Department of Health  
and Human Services,

Defendant.

Civil Action No.:  
1:15-CV-13530-NMG

**ANSWER TO COUNTS I, II, III, IV, V, VI, AND VII OF THE COMPLAINT**

Defendant, the Secretary of the U.S. Department of Health and Human Services,  
responds to Counts I, II, III, IV, V, VI, and VII of the Complaint as follows:

**PRELIMINARY STATEMENT**

1. Paragraph One contains characterizations of Plaintiff's actions that do not require a response. To the extent that a response is required, Defendant admits that judicial review of the final decision of the Defendant arises under the Medicare statute at 42 U.S.C. § 1395 *et seq.* and denies that jurisdiction arises under the Administrative Procedures Act.
2. Defendant admits that the administrative record reflects that Plaintiff has received treatment for Type I diabetes for approximately 30 years. Defendant lacks sufficient knowledge or information to form a belief as to the remaining allegations in Paragraph 2.
3. Paragraph 3 contains conclusions of law that do not require a response. To the extent that a response is required, they are denied.
4. Defendant admits that the administrative record reflects that Plaintiff was prescribed a continuous glucose monitor ("CGM") before she became eligible for Medicare.

5. Paragraph 5 contains conclusions of law that do not require a response. To the extent that a response is required, they are denied.
6. Paragraph 6 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant refers 42 U.S.C. § 1395ff(f)(1)(B), 45 C.F.R. § 405.1060(a), and the Medicare National Coverage Determination Manual (“MNCDM”), CMS Pub. No. 100-3, § 40.2.
7. Paragraph 7 contains conclusions of law that do not require a response. To the extent a response is required, Defendant refers this Court to NHIC, Corp., Local Coverage Determination (LCD) for Glucose Monitors, L11530 for a more complete statement on coverage of blood glucose monitors by Medicare.
8. Defendant denies the allegations in Paragraph 8.
9. Paragraph 9 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant refers this Court to 42 C.F.R. § 405.1062 and NHIC, Corp., Local Coverage Article for Glucose Monitors - Policy Article A33614 (2005) for a more complete statement on NHIC’s coverage of continuous glucose monitors.
10. Defendant admits that NHIC, Corp. denied Plaintiff’s claims for disposable sensors and transmitters for use with her CGM for dates of service from March 12, 2012, through September 17, 2012.
11. Defendant admits the allegations in Paragraph 11.
12. Defendant admits that the MAC rendered a decision on September 25, 2015. The remaining allegations in Paragraph 11 are conclusions of law that do not require a response. To the extent that a response is required, Defendant refers this Court to 42 U.S.C. § 1395ff(d)(2),(3), 42 C.F.R. § 405.1100, 405.1132 for an explanation of the

timeframe in which the AC must render a decision and Plaintiff's right to escalate if a decision is not issued.

13. Defendant admits that the AC's decision is the final decision of Defendant for purposes of judicial review. Defendant denies all remaining allegations in Paragraph 13.
14. Paragraph 14 contains characterizations of Plaintiff's actions that do not require a response. To the extent that a response is required, they are denied, and Defendant asserts that Plaintiff is not entitled to her requested relief.

### **Jurisdiction and Venue**

15. Defendant admits that this Court has subject matter jurisdiction under 42 U.S.C. §§ 405(g) and 1395ff(b). Defendant denies that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1361.
16. Paragraph 16 contains assertions of venue to which no response is required. To the extent a response is required, Defendant is without sufficient knowledge or information to admit or deny venue under 42 U.S.C. §§ 405(g) and 1395ff(b), and leaves Plaintiff to her proof.

### **Parties**

17. Defendant admits that the administrative record reflects the allegations in Paragraph 17.
18. Defendant lacks sufficient knowledge or information sufficient to form a belief as to the allegations in Paragraph 18 and denies the allegations.
19. Paragraph 19 contains characterizations of Plaintiff's actions that do not require a response. To the extent that a response is required, they are admitted.
20. Defendant admits that Sylvia Mathews Burwell is the Secretary of the Department of Health and Human Services. The remainder of Paragraph 20 contains characterizations

of Plaintiff's action that do not require a response. To the extent a response is required, Plaintiff admits that the Secretary, in her legal capacity, is the proper Defendant in appeals of the Secretary's final decision to the extent authorized by 42 U.S.C. §§ 405(g) and 1395ff(b).

## **FACTUAL BACKGROUND**

### **A. General Background of the Medicare Program**

21. Paragraph 21 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant refers this Court to 42 U.S.C. § 1395 *et seq.*

Defendant admits that this action arises under Medicare Part B.

22. Paragraph 22 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant refers this Court to 42 U.S.C. § 1395hh.

23. Paragraph 23 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant refers this Court to 42 U.S.C. § 1395hh.

### **B. Medicare Coverage and Payment of DMEPOS**

24. Paragraph 24 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant refers this Court to 42 U.S.C. §§ 1395j - 1395w-6, 1395y.

25. Paragraph 25 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant refers this Court to 42 U.S.C. § 1395x(n) and 42 C.F.R. § 414.202.

26. Paragraph 26 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant refers this Court to the Medicare Benefit Policy Manual ("MBPM"), CMS Pub. No. 100-02, Ch. 15, §110.

27. Defendant admits that pursuant to 45 C.F.R. § 162.1002, Defendant has adopted medical code data sets, including the codes identified in the Healthcare Common Procedure Coding System (“HCPCS”), which include codes for durable medical equipment. Defendant contends that a number of factors are used to determine whether a medical device should be assigned a code and those factors are laid out on CMS’ website at [https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCS\\_Decision\\_Tree\\_and\\_Definitions.pdf](https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCS_Decision_Tree_and_Definitions.pdf).
28. Paragraph 28 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant refers this Court to 42 U.S.C. §§ 1395x(n), 1395m, 42 C.F.R. § 414.210.
29. Paragraph 29 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits that Defendant has contracted the authority to make initial Medicare coverage determinations to Medicare administrative contractors pursuant to 42 U.S.C. § 1395kk-1. Defendant admits that DMACs make initial coverage determinations related to the Medicare coverage of DME in accordance with 42 U.S.C. §§ 1395kk-1 and 1395ff. Defendant contends that, if the coverage determination is challenged, the procedures set forth in 42 U.S.C. § 1395ff governs.
30. Paragraph 30 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits that after a claim is filed with the appropriate contractor, the contractor must determine if the item or service is covered under the Medicare statute, *see* 42 U.S.C. § 1395ff, 42 C.F.R. § 405.900 *et seq.*

**C. Medicare Coverage and Glucose Monitoring**

31. Paragraph 31 contains conclusions of law that do not require a response. To the extent a response is required, Defendant refers this Court to the definitions of national coverage determination set forth in 42 U.S.C. § 1395ff(1)(B) and 42 C.F.R. § 405.1060(a).
32. Paragraph 32 contains a conclusion of law that does not require a response. To the extent a response is required, Defendant admits.
33. Paragraph 33 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant admits that Defendant issued the MNCDM, CMS Pub. No. 100-03, § 40.2, which sets forth when home blood glucose monitors are covered by Medicare.
34. Paragraph 34 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant refers to MNCDM, CMS Pub. No. 100-03, § 40.2 as Plaintiff's language characterizing the section is inexact.
35. Defendant denies the allegations in Paragraph 35.
36. Paragraph 36 contains conclusions of law that do not require a response. To the extent a response is required, Defendant refers to 42 U.S.C. § 1395ff(f)(2)(B).
37. Paragraph 37 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant admits that the Medicare Program Integrity Manual ("MPIM"), Ch. 13, § 13.7 offers guidance to its contractors on issuing local coverage determinations.
38. Paragraph 38 contains conclusions of law that do not require a response. To the extent a response is required, Defendant refers to 42 C.F.R. § 405.1062.

39. Paragraph 39 contains conclusions of law that do not require a response. To the extent a response is required, Defendant denies the allegations in Paragraph 39 and states that NHIC, Corp (not National Government Services) issued Local Coverage Determination for Glucose Monitors, L11530. The LCD's original effective date was October 1, 1993 and the revision effective date was August 1, 2013. Defendant refers to LCD L11530 as Plaintiff's language characterizing it is inexact.

40. Paragraph 40 contains conclusions of law that do not require a response. To the extent a response is required, Defendant denies.

41. Paragraph 41 contains conclusions of law that do not require a response. To the extent a response is required, Defendant denies and refers to MPIM, Ch. 13, § 13.1.3 and 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003).

42. Paragraph 42 contains are conclusions and characterizations that do not require a response.

**D. The Process for Appeals of Medicare Claims Decisions**

43. The allegations in Paragraph 43 are conclusions of law that do not require a response. To the extent a response is required, Defendant refers to 42 U.S.C. § 1395ff, 42 C.F.R. § 405.904(a)(2).

44. Paragraph 44 contains a conclusion that does not require a response.

45. Paragraph 45 contains a conclusions of law that does not require a response. To the extent a response is required, Defendant admits that the first step in challenging an initial determination regarding Medicare coverage is to request a redetermination with the Medicare administrative contractor pursuant to 42 C.F.R. §§ 405.940 – 405.958.

46. Paragraph 46 contains conclusions of law that do not require a response. To the extent a response is required, Defendant refers to 42 C.F.R. § 405.956, which more precisely sets forth the elements that the contractor's written notice of redetermination must contain.
47. Paragraph 47 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits and refers this Court to 42 C.F.R. §§ 405.960 – 405.978 for further discussion of the reconsideration process.
48. Paragraph 48 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits and refers to 42 C.F.R. §§ 405.1000- 405.1064 for further discussion of the ALJ review process.
49. Paragraph 49 contains conclusions of law that do not require a response. To the extent a response is required, Defendant avers that an ALJ is bound to follow an NCD but notes that it is within the purview of an ALJ to review the facts of a particular case to determine whether an NCD applies and, if so, whether the NCD was applied correct, *see* 42 C.F.R. § 405.1060(b).
50. Paragraph 50 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits that LCDs are not binding on an ALJ but notes that an ALJ (and the MAC) is required to give substantial deference to the LCD if it is applicable to a particular case, *see* 42 C.F.R. § 405.1062(a).
51. Paragraph 51 contains conclusions of law that do not require a response. To the extent a response is required, Defendant avers that, unless the appellant is entitled to relief pursuant to 42 C.F.R. §§ 426.460(b)(1), 426.488(b), or 426.560(b)(1), the ALJ applies the LCD in place on the date the item or service was provided, *see* 42 C.F.R. § 1034(c).



52. Paragraph 52 contains conclusions of law that do not require a response. To the extent a response is required, Defendant denies and refers to 42 C.F.R. § 405.1062(a).
53. Paragraph 53 contains conclusions of law that do not require a response. To the extent a response is required, Defendant refers this Court to 42 C.F.R. § 405.1016 for an accurate discussion of the timeframe and notes that 42 U.S.C. § 1395ff(d)(3) and 42 C.F.R. § 405.1104 provide an appellant a right to request escalation if he/she does not receive a decision in that timeframe.
54. Paragraph 54 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits.
55. Paragraph 55 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits that an NCD is binding on the AC and denies the remainder of the paragraph.
56. Paragraph 56 contains conclusions of law that do not require a response. To the extent a response is required, Defendant refers this Court to 42 C.F.R. § 405.1100 for an accurate discussion of the timeframe and notes that 42 U.S.C. § 1395ff(d)(3) and 42 C.F.R. § 405.1132 provide an appellant a right to request escalation if he/she does not receive a decision in that timeframe.
57. Paragraph 57 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits.
58. Paragraph 58 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits.
59. Paragraph 59 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits refers to 42 C.F.R. § 405.1130.

**E. The Process for Challenging an LCD**

60. Paragraph 60 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant admits.
61. Paragraph 61 contains conclusions of law that do not require a response. To the extent that a response is required, Defendant admits.
62. Paragraph 62 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits and refers to the separate claims appeal process set forth in part 405, subparts G and H (*see* 42 C.F.R. § 426.310(a)) and Defendant notes that the ALJ evaluates whether the claim is acceptable before conducting review (*see* 42 C.F.R. § 426.410).
63. Paragraph 63 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits and refers to 42 C.F.R. § 426.418(a), which discusses what the record may include.
64. Paragraph 64 contains conclusions of law that do not require a response. To the extent a response is required, Defendant refers this Court to 42 C.F.R. §§ 426.400 – 426.490 for a discussion of the scope of the ALJ's review.
65. Paragraph 65 contains conclusions of law that do not require a response. To the extent a response is required, Defendant denies and refers to 42 C.F.R. § 426.460.

**STATEMENT OF FACTS AND PRIOR PROCEEDINGS**

**A. Continuous Glucose Monitoring and Brittle Diabetics**

66. Defendant lacks sufficient knowledge or information sufficient to form a belief as to the allegations in Paragraph 66.

67. Defendant lacks sufficient knowledge or information sufficient to form a belief as to the allegations in Paragraph 67.
68. Defendant lacks sufficient knowledge or information sufficient to form a belief as to the allegations in Paragraph 68.
69. Defendant lacks sufficient knowledge or information sufficient to form a belief as to the allegations in Paragraph 69.
70. Defendant admits that the administrative record reflects that CGMs operate by measuring the glucose level in the interstitial fluid under the skin. Defendant denies that the administrative record reflects that this measurement directly reflects the glucose concentration in the blood.
71. Defendant admits the allegations in Paragraph 71 but contends that the FDA approval limits its approved use to use in conjunction with finger stick blood glucose measurements.
72. Defendant lacks knowledge or information sufficient to form a belief as to truth or falsity.
73. Paragraph 73 contains a conclusion of law that does not require a response. To the extent a response is required, Defendant denies.
74. Defendant admits that the administrative record contains articles from the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring, the American Diabetes Association, the Endocrine Society, the Société Francophone du Diabète, the EVADIAC Group, the European Society for Pediatric Endocrinology, the Pediatric Endocrine Society, and the International Society for Pediatric and Adolescent Diabetes. The remainder of the paragraph contains characterizations of their contents that do not require a response.

75. Defendant admits that the administrative record contains Resolution 126 issued by the American Medical Association. The remainder of the paragraph contains a characterization of fact to which no response is required.

76. Paragraph 76 contains conclusions that require no response. To the extent a response is required, Defendant denies.

77. Defendant lacks sufficient knowledge or information sufficient to form a belief as to the allegations in Paragraph 77 and leaves Plaintiff to her proof.

78. Defendant admits that the administrative record contains a Review from the Agency for Health Care Research and Quality titled Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness. The remainder of Paragraph 78 is a characterization of facts to which no response is required.

**B. The Proceedings Below Relating to the Claims at Issue in this Action**

79. Defendant admits the allegations in Paragraph 79.

80. Defendant admits that the administrative record reflects the allegations in Paragraph 80.

81. Defendant lacks sufficient knowledge or information sufficient to form a belief as to the allegations in Paragraph 81.

82. Defendant admits that the administrative record reflects that Plaintiff's physician prescribed her a continuous glucose monitor. Defendant lacks sufficient knowledge or information sufficient to form a belief as to the remainder of Paragraph 82.

83. Paragraph 83 contains conclusions of law that do not require a response. To the extent a response is required, Defendant denies the allegations.

84. Defendant lacks sufficient knowledge or information sufficient to form a belief as to the allegations in Paragraph 84.

85. Defendant admits the NHIC, Inc. denied Plaintiff's claim for disposable sensors and transmitters for use with her CGM from dates of service March 12, 2012 through September 17, 2012.
86. Defendant admits the allegations in Paragraph 86.
87. Defendant admits that the Office of Medicare Hearings and Appeals received copies of Plaintiff's Request for Medicare Hearing by an Administrative Law Judge on July 8, 9, and 11, 2013.
88. Defendant admits the allegations in Paragraph 88.
89. Defendant admits that the administrative record contains the hearing testimony of Plaintiff's healthcare provider, Dr. Richard Beaser. The remainder of the paragraph contains characterizations of the record that require no response.
90. Defendant admits that the administrative record contains the hearing testimony of Plaintiff's healthcare provider, Dr. Richard Beaser. The remainder of the paragraph contains characterizations of the record that require no response.
91. Defendant admits that the administrative record contains the hearing testimony of Plaintiff's healthcare provider, Dr. Richard Beaser. The remainder of the paragraph contains characterizations of the record that require no response.
92. Paragraph 92 contains conclusions of law that require no response. To the extent a response is required, Defendant refers this Court to 42 C.F.R. § 405.1036(f)(1).
93. Paragraph 83 contains conclusions of law that require no response. To the extent a response is required, Defendant admits that the ALJ's Decision was issued on February 6, 2014 and Defendant refers this Court to 42 C.F.R. § 405.1016 that sets forth the required timeframe and notes that 42 U.S.C. § 1395ff(d)(3) and 42 C.F.R. § 405.1104 provide an

appellant a right to request escalation if he/she does not receive a decision in that timeframe.

94. Defendant admits that Plaintiff timely filed her Request for Review of Administrative Law Judge Medicare Decision on March 24, 2014.

95. Defendant admits that on December 29, 2014 the Civil Remedies Division of the Departmental Appeals Board received the Complaint challenging LCD L11530 and LCA A33614 and that the Complaint was timely received. Defendant avers that the Complaint was based on an initial denial notice not at issue here.

96. Defendant denies the allegations in Paragraph 96.

97. Defendant admits that on September 11, 2015, ALJ Sickendick issued a Ruling.

Defendant denies the remaining allegations in Paragraph 97 and contends that the Ruling concluded that the record for the challenged LCD was not complete and adequate to support the validity of the LCD and that further discovery and case development were ordered.

98. Defendant denies the allegations in Paragraph 98 and avers that ALJ Sickendick held that he had “no jurisdictional authority to review a determination by CMS that an item is not DME.”

99. Defendant admits that the AC received Plaintiff’s request to escalate the case to federal district court on September 16, 2015. The remaining allegations in Paragraph 99 are conclusions of law that require no response. To the extent a response is required, Defendant refers to 42 U.S.C. § 1395ff(b) and 42 C.F.R. §§ 405.1100, 405.1132.

100. Paragraph 100 contains conclusions of law that do not require a response. To the extent a response is required, Defendant admits that 42 C.F.R. § 405.1132 governs how the AC must respond after receiving a request for escalation and denies all remaining allegations.
101. Defendant denies that the case had been pending at the AC for more than 550 days. Defendant admits that the AC affirmed the ALJ's denial of Medicare coverage and modified the basis of denial.
102. Paragraph 102 contains characterizations and conclusions of law that do not require a response. To the extent that a response is required, Defendant denies that the AC's decision was without support and ignored Judge Sickendick's findings and admits the remaining allegations.
103. Paragraph 103 contains characterizations and conclusions of law that do not require a response. To the extent a response is required, Defendant denies.
104. Paragraph 104 contains characterizations and conclusions of law that require no response. To the extent a response is required, Defendant denies.

## **COUNT I**

### **Violation of APA under 5 U.S.C. § 706 (CGM is Not Precautionary and Not Excluded from Coverage)**

105. Defendant hereby incorporates by reference responses to paragraphs 1 to 104.
106. Paragraph 106 contains conclusions of law that require no response. To the extent that a response is required, Defendant denies.
107. Paragraph 107 contains conclusions of law that do not require a response. To the extent a response is required, Defendant denies, and Plaintiff is not entitled to the requested relief.

108. Paragraph 108 contains conclusions of law that do not require a response. To the extent a response is required, Defendant denies.

109. Paragraph 109 contains conclusions of law that require no response. To the extent a response is required, Defendant denies, and Plaintiff is not entitled to the requested relief.

## **COUNT II**

### **Violation of APA under 5 U.S.C. § 706 (CGM is Covered Under NCD 40.2)**

110. Defendant hereby incorporates by reference answers to paragraphs 1 to 109.

111. Paragraph 111 contains conclusions of law that require no response. To the extent that a response is required, Defendant denies.

112. Paragraph 112 contains conclusions of law that require no response. To the extent that a response is required, Defendant denies, and Plaintiff is not entitled to the requested relief.

## **COUNT III**

### **Violation of APA under 5 U.S.C. § 706 (Failure to Follow the NCD)**

113. Defendant hereby incorporates by reference answers to paragraphs 1 to 112.

114. Paragraph 114 contains conclusions of law that require no response. To the extent that a response is required, Defendant denies, and Plaintiff is not entitled to the requested relief.

## **COUNT IV**

### **Violation of APA under 5 U.S.C. § 706 (CGM is Not Non-Covered Under LCD L27231)**

115. Defendant hereby incorporates by reference answers to paragraphs 1 to 114.



116. Paragraph 116 contains conclusions of law that require no response. To the extent a response is required, Defendant denies and Plaintiff is not entitled to the requested relief.

117. Paragraph 117 contains conclusions of law that require no response. To the extent that a response is required, Defendant denies, and Plaintiff is not entitled to the requested relief.

### **COUNT V**

#### **Violation of APA under 5 U.S.C. § 706 (Failure to Follow the LCD)**

118. Defendant hereby incorporates by reference answers paragraphs 1 to 117.

119. Paragraph 119 contains conclusions of law that require no response. To the extent a response is required, Defendant denies, and Plaintiff is not entitled to the requested relief.

120. Paragraph 120 contains conclusions of law that require no response. To the extent that a response is required, Defendant denies, and that Plaintiff is not entitled to the requested relief.

### **COUNT VI**

#### **Violation of APA under 5 U.S.C. § 706 (Deference to the Article)**

121. Defendant hereby incorporates by reference answers to paragraphs 1 to 121.

122. Paragraph 122 contains conclusions of law that require no response. To the extent a response is required, Defendant denies, and Plaintiff is not entitled to her requested relief.

123. The allegations in Paragraph 123 are conclusions of law rather than averments of fact which do not require a response. To the extent a response is required, Defendant denies the allegations in Paragraph 123 and asserts that Plaintiff is not entitled to the requested relief.

124. Paragraph 124 contains conclusions of law that require no response. To the extent that a response is required, Defendant denies.

## **COUNT VII**

### **Violation of APA under 5 U.S.C. § 706 (Failure to follow the Statutory Definition of DME)**

125. Defendant hereby incorporates by reference answers 1 to 124 herein.

126. Paragraph 126 contains conclusions of law that require no response. To the extent a response is required, Defendant denies, and that Plaintiff is not entitled to the requested relief.

127. Paragraph 127 contains conclusions of law that require no response. To the extent a response is required, Defendant denies, and Plaintiff is not entitled to the requested relief.

## **REQUESTED RELIEF**

Paragraphs 1 through 7 of the Requested Relief section of the Complaint consist of a prayer for relief, to which no responsive pleading is required. However, if a response is required, Defendant denies that Plaintiff is entitled to the relief sought. To the extent that the prayer for relief is deemed to allege facts to which a response is required, Defendant denies the allegations set forth in Paragraphs 1 through 7 of the Request Relief section of the Complaint.

Defendant denies each and every allegation not previously specifically admitted or otherwise qualified herein. Defendant denies that Plaintiff is entitled to the benefits that are the subject matter of this action.

## **AFFIRMATIVE DEFENSES**

1. Plaintiff's challenges to the Secretary's final decision are governed exclusively by the Medicare statute; therefore, this Court should not exercise jurisdiction over Plaintiff's

APA counts. *See* 42 U.S.C. § 405(h), *incorporated into the Medicare statute by* 42 U.S.C. § 1395ii.

2. This Court retains jurisdiction over this action pursuant to 42 U.S.C. § 405(g), incorporated into the Medicare statute by 42 U.S.C. § 1395ff, and this Court should review Plaintiff's counts in accordance with the substantial evidence standard of review set forth at 42 U.S.C. § 405(g) and not the APA standard of review set forth at 5 U.S.C. § 706.
3. Defendant's findings are supported by substantial evidence and are conclusive. In accordance with 42 U.S.C. § 405(g), as incorporated into the Medicare statute by 42 U.S.C. § 1395ff, Defendant files, as part of the answer, a certified copy of the transcript of the records, including the evidence upon which the findings and decisions complained of are based.
4. Defendant denies that Plaintiff is entitled to the Medicare benefits that are the subject of this action and states that the Defendant's decision is supported by substantial evidence and is in accord with applicable law and regulations.
5. With respect to Plaintiff's request for "[s]uch other relief as this Court may deem and consider appropriate[.]" Defendant states that this Court has no jurisdiction to enter any judgment other than that provided for in 42 U.S.C. § 405(g).
6. With respect to Plaintiff's request for "[a]n order awarding legal fees and costs of suit incurred by Plaintiff[.]" Defendant states that there are no provisions in the Social Security Act or the Medicare statute to permit costs to be charged against the Defendant. However, certain costs charged against the government of the United States can be paid from Judgment by the Department of the Treasury, if so ordered by the court pursuant to

31 U.S.C. § 1304. The award must be certified by the Office of the United States Attorney to the Department of Treasury for payment.

7. With respect to Plaintiff's request for attorney fees, should Plaintiff prevail and file an application for fees against the United States in accordance with the requirements of 28 U.S.C. § 2412, enacted as part of the Equal Access to Justice Act, Defendant reserves the right to oppose any award under that statute.

WHEREFORE, Defendant requests that the Court dismiss the Complaint, with costs and disbursements, and for judgment in accordance with 42 U.S.C. § 405(g), affirming the Secretary's decision.

Respectfully submitted,

CARMEN ORTIZ  
UNITED STATES ATTORNEY

/s/ Anita Johnson  
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Certificate of Service

I hereby certify that the foregoing will be filed through the electronic filing system of the Court, which system will serve counsel for Plaintiff electronically, on this 18<sup>th</sup> day of November 2016.

/s/ Anita Johnson